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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,663	11/12/2003	Gary T. Neel	02-1134-F	9299

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EXAMINER	
WALLENHORST, MAUREEN	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/706,663	NEEL ET AL.	
	Examiner	Art Unit	
	Maureen M. Wallenhorst	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *42-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *42-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/9/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The disclosure is objected to because of the following informalities: On page 2 of the specification in the section entitled "Cross-Reference to Related Applications", the phrase – now US Patent no. 6,743,635, issued on June 1, 2004—should be inserted after the phrase "US Patent Application no. 10/286,648, filed November 1, 2002," in order to update the status of this parent application.

Appropriate correction is required.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 42-43 and 47-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over White et al (US Patent no. 5,366,609, submitted in the Information Disclosure Statement filed on August 9, 2004).

White et al teach of a biosensing meter with a pluggable memory key. The biosensing meter 10 includes a slot 16 for receiving a disposable sample strip 18. Sample strip 18 contains a reaction zone 20 having a pair of electrodes 24 and 26 therein. A layer of enzymatic reactants overlays the electrodes 24 and 26 in the reaction zone 20 and provides a substrate on which an analyte-containing fluid sample is placed. The sample strip 18 has an opening 28 at its distal end that exposes electrodes 24 and 26 and renders them available for electrical connection with biosensing meter 10. A pluggable/removable ROM (read only memory) key 30 mates with an electrical receptacle within the meter 10 so as to be in electrical communication with control circuitry therein. ROM key 30 includes a carrier surface 34 having thereon a circuit board in the form of a memory chip 32. A plurality of electrical contacts or leads 36 and 38 emanate from the ROM chip 32. Substrate 34 is insulating and provides a support for the chip 32. When ROM key 30 is inserted into the meter 10, a plurality of flexible contacts internal to the meter 10 make connection with the contacts 36 and 38 and enable a microprocessor within the meter 10 to access data stored in the ROM chip 32. A temperature sensor 54 is positioned within the meter 10. A microprocessor 59 provides overall control of the operation of the meter 10 in combination with data read from ROM key 30. ROM key 30 is pluggable into the meter 10 and contains non-volatile memory that includes constants and other data required to carry out analyte-determination procedures. Generally, ROM key 30 will contain constants and procedure

code that enables the meter 10 to adjust its measurement parameters to match the specific batch characteristics of disposable sample strips 18. ROM key 30 will also contain a large number of additional variable values that control the operation of the microprocessor 59 in performing actual analyte determination tests. Data stored in the ROM key 30 includes measurement delay times, incubation times, the number of measurements to be taken during a measurement period, various thresholds against which voltage levels are to be compared, values of excitation voltage levels to be applied to the sample strips during a test procedure, glucose value conversion factors, temperature compensation correction procedures, and a variety of other test threshold values. See Figures 1-3 and columns 4-6 in White et al. The ROM key 30 taught by White et al is "keyed" for inserting into the meter in a preferred orientation since the ROM key has one end containing the chip 32 and electrical contacts 36, 38 and an opposite end containing three grooves (see Figure 2 of White et al) which serve to distinguish the two ends from one another. The grooved end serves to distinguish the end of the key to be gripped by a user for insertion into the meter, and the end containing the memory chip and electrical contacts serves to distinguish the end to be inserted into the meter.

White et al fail to teach that one of the electrical contacts 36 and 38 in the ROM key is a ground contact and one is a voltage supply contact. However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to realize or understand that one of the electrical contacts 36, 38 in the pluggable ROM key taught by White et al is a ground contact and one is a voltage supply contact so that the key can become electrically connected to the meter and form an electric circuit therewith, or in order words, so that the key can accept and

conduct current or voltage to and from the meter so that the meter can read the data stored on the key.

6. Claims 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over White et al in view of Deweese et al (US Patent no. 6,377,894, also submitted in the IDS filed on August 9, 2004). For a teaching of White et al, see previous paragraphs in this Office action. White et al fail to teach that the data stored on the ROM key can include information such as the brand and expiration date of the test strip inserted into the meter for analysis, and the model of the meter.

Deweese et al teach of an analyte test instrument 100 in which a calibration data storage strip including a memory device can be inserted into the test port of the instrument. A calibration strip 270 includes a ROM 280 and electrical contacts 260 for making connection with the test port of the instrument 100. The ROM encodes information on the algorithms for performing a strip-based assay and a list of parameters that are essential in characterizing analyte chemistries, test strips and marketing requirements. The calibration strip 270 delivers the necessary parameters and procedures to the instrument 100 to characterize an assay. The data included on the ROM 280 can include instrument parameters such as meter type, test strip parameters such as expiration date and brand, and analyte parameters. See lines 35-67 in column 6, lines 50-67 in column 8, and lines 20-30 in column 9 of Deweese et al.

Based upon the combination of White et al and Deweese et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to store on the ROM key taught by White et al information such as the brand and expiration date of the test strip inserted into the meter for analysis, and the model of the meter since Deweese et al teach that

such information is standard on an ROM device intended for use and downloading by an electrochemical meter used to measure the concentration of chemical analytes.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Neel et al, which corresponds to the parent application of this instant application.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

January 10, 2005

Maureen M. Wallenhorst
MAUREEN M. WALLENHORST
PRIMARY EXAMINER
GROUP [redacted] 1700